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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/489,198 | 01/20/2000 | Shigeaki Kato | 06501-054001 | 5541 |

7590 04/19/2002

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EXAMINER

MURPHY, JOSEPH F

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1646 | 17 |

DATE MAILED: 04/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/489,198 | KATO ET AL. |
| | Examiner Joseph F Murphy | Art Unit 1646 |

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 February 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-27 is/are pending in the application.
 - 4a) Of the above claim(s) 1-7 and 12-27 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 8-11 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5,6</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group X, claims 8-11 in Paper No. 16, 2/13/2002 is acknowledged. The traversal is on the ground(s) that the inventions are not independent and distinct, and there is no burden to search. This is not found persuasive because claims 26 and 27 are directed to methods of screening for transcriptional regulatory factors, while claims 8-121 are directed to methods of screening for polypeptides that convert precursor ligands to an active form. The methods of claims 26-27 involve examining protein-protein interactions, while the methods of claims 8-11 involve ligand binding, and are thus have a separate status in the art and would require non-coextensive searches. Claims 1-7, 12-27 withdrawn from consideration pursuant to 37 CFR 1.142(b).

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8-11 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP

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§ 2172.01. The omitted steps are: the converted ligand molecule, after conversion to the active form, binds to and activates the nuclear receptor.

Claims 8-11 are vague and indefinite due to the recitation of the term "ligand precursor". In the specification, the term ligand is defined as comprising naturally-occurring compounds as well as synthetic compounds (page 10, lines 1-3). A definition is not provided for a "ligand precursor" and it is not clear if the ligand precursor must be converted to activate expression of the reporter gene, or if the compound must only be capable of conversion to an active form.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9 and 11 are rejected under 35 U.S.C. 102(a) as being anticipated by Zhao et al. (1997).

Zhao et al. teaches a method of measuring the effect of vitamin d analogs on the dimerization of the vitamin d3 receptor with RXR, using the yeast two hybrid system (page 368, column 1, first full paragraph). This meets the limitations of the indicated claims, because the method taught by Zhao et al. involves transfection of a test gene into a cell, wherein the test gene comprises a nucleic acid sequence encoding a nuclear receptor. A separate vector comprising a binding sequence, as well as a reporter gene is also transfected into the cell. The analogs can be

considered ligand "precursors", the analogs bind to the nuclear receptor, and the activity of the reporter molecule is measured (page 369, Figure 3). Thus all the limitations of the method as set forth in claims 9 and 11 are met.

Claims 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 9621677 (Moore et al.).

WO 9621677 discloses methods of determining whether a test protein is capable of interacting with a nuclear hormone receptor, the RXR receptor. WO 9621677 at 2. Further disclosed are methods where the host cell is further treated with a ligand, and identifying a ligand-dependent interacting protein by its ability to increase expression of a reporter gene in both the presence and absence of ligand treatment. Id. at 3. This meets the limitations of the indicated claims, because the method taught by WO 9621677 involves transfection of a test gene into a cell, treating a cell with ligand, and isolating the positive clones. Id. at 12. Thus the limitations of claims 8 and 9 are anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 9621677

(Moore et al.).

WO 9621677 discloses methods of determining whether a test protein is capable of interacting with a nuclear hormone receptor, the RXR receptor. WO 9621677 at 2. Further disclosed are methods where the host cell is further treated with a ligand, and identifying a ligand-dependent interacting protein by its ability to increase expression of a reporter gene in both the presence and absence of ligand treatment. Id. at 3. This meets the limitations of the indicated claims, because the method taught by WO 9621677 involves transfection of a test gene into a cell, treating a cell with ligand, and isolating the positive clones. Id. at 12. WO 9621677 further discloses that the methods can be practiced using the VDR as a heterodimer partner with the RXR receptor. Id. at 34. Thus, it would have been obvious to one of skill in the art at the time the invention was made to practice the method taught by WO 9621677 involves transfection of a test gene into a cell, treating a cell with ligand, and isolating the positive clones.

Conclusion

No claim is allowed.

Advisory Information

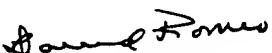
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
April 16, 2002



DAVID S. ROMEO
PRIMARY EXAMINER